Transcript of FDA Media Briefing on FDA's Proposal to Extend its Tobacco Authority to Additional Tobacco Products, Including E-cigarettes
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Coordinator: Welcome and thank you for standing by. At that time, all participants are in a listen-only mode. During today's Q&A session, if you'd like to ask a question, you may press Star 1. Today's call is also being recorded. If you have any objections, you may disconnect at this time. Now, I'd like to turn today's meeting over to Ms. Jennifer Haliski. Ma'am, you may begin.

Jennifer Haliski: Thank you very much. Good afternoon and thank you for participating in today's call. My name is Jenny Haliski and I'm with the FDA's Office of Media Affairs. This is a briefing for credentialed media to discuss FDA's proposed rule to extend its authority to new types of tobacco products. By now, FDA's news release on this announcement has posted to our website and has been distributed to news media.

We are honored to start off this call with some brief remarks by Kathleen Sebelius, Secretary of the United States Department of Health and Human Services. I'm also joined by FDA Commissioner Dr. Margaret Hamburg and Mitch Zeller, Director of the FDA's Center for Tobacco Products or CTP. After Secretary Sebelius' brief remarks, Dr. Hamburg will provide some opening comments about today's action. Further remarks and Mr. Zeller's comments will be followed by a question and answer period. Reporters will be in listen-only mode until we open the call up for questions.

When asking a question, please state your name and affiliation. Also, please limit yourself to one question and one follow-up question so that we can get to as many questions as possible. Without further ado, I will turn the call over to HHS Secretary Kathleen Sebelius. Secretary Sebelius.

Kathleen Sebelius: Well, thank you so much Jenny and thank you all for joining us today. Since we issued our call in January to make this next generation tobacco free, we've already seen some very positive developments. CVS, for example, made the landmark announcement that they will stop selling cigarettes and other tobacco products. The State of Georgia announced that all of public colleges and universities will ban smoking on their campuses and the FCA launched a ground breaking media campaign aimed at convincing teens not to smoke.

At the same time, CDC moved its advertising campaign forward which is aimed at helping adults to stop smoking. Now today, with the new proposed FDA rule on deeming, we're taking another very important step toward the goal of a tobacco-free generation. When this deeming rule is finalized, the FDA will be able to regulate new and emerging products like electronic cigarettes. We know that the use of novel products, like so called e-cigs, are on the rise, particularly among young people.

CDC has found, for example, that the use of e-cigarettes among middle and high school students doubled between 2011 and 2012. I think that bears repeating. The use of these products doubled. What we don't know yet is the full impact and ramification that these products have on our nation’s health. We don't yet have a full understanding as to whether these products serve as a gateway to the use of regular cigarettes and we don't know how they influence the behavior of current smokers. This proposed deeming rule would allow us to gain a more robust understanding, and if necessary, an ability to take action to mitigate potential harms.

By bringing additional tobacco products under FDA's regulatory umbrella, we'll gain some significant new tools. Tools like tobacco product regulation

that are informed by the latest science, tools that are designed to strengthen public health, tools that are designed to save lives. The fact of the matter is, for all the progress we've made since the first Surgeon General's report 50 years ago, tobacco use remains the leading cause of preventable death and disease here in the United States and also around the world. Year after year after year it claims nearly a half a million American lives: our parents, our children, our colleagues, our friends.

Statistics tell us that most Americans who will die from smoking this year began smoking when they were kids. Every day, more than 3200 children try their first cigarette and each day, 2100 of those kids and young adults become daily smokers and if we fail to reverse those trends, 5.6 million American children who are alive today will die prematurely due to smoking.

Now, as I turn things over to Commissioner Hamburg, let me just say that the FDA's team at the Center for Tobacco Products has been working tirelessly to prepare this proposed rule. I want to thank commissioner Hamburg -- one of our great health leaders in this country -- and Mitch Zeller, the terrific and zealous director of the FDA's Center for Tobacco Products, and their whole team for all of this hard work. And with that, it's my pleasure to turn the call over to Commissioner Hamburg. Peggy.

Margaret Hamburg: Well, thank you so much Madam Secretary, and thank you for all of your leadership and support. And good afternoon to all of you that have joined us on this call. Today is an important moment for consumer health and protection. Today, FDA is issuing a historic proposal that, if finalized, could bring many new types of tobacco products under the FDA's authority. This new proposed rule would extend the agency tobacco product authority to cover additional products that meet the legal definition of the tobacco product. Products that would be deemed to be subject to FDA regulation would include

currently unregulated marketed products such as electronic cigarettes, the guards, pipe tobacco, certain dissolvable products that are not smokeless tobacco, nicotine gels and water pipe tobacco.

The FDA current regulates cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, as tobacco products under the 2009 Family Smoking Prevention and Tobacco Control Act. But in that law, Congress gave the FDA the authority to deem other tobacco products, and these are products that don't include drugs, devices or combination products, subject to chapter nine of the Food, Drug and Cosmetic Act. Products made or derived from tobacco that are marketed for therapeutic purposes, such as for smoking cessation, will continue to be regulated as medical products under the FDA's existing drug and device authority in the Food, Drug and Cosmetic Act.

Science-based product regulation is one of the most powerful forms of consumer protection that can help reduce the public health burden of tobacco use in the American public including youth. Under final deeming rules, the FDA would extend important existing requirements and restrictions to additional tobacco products. To date, the agency has not been able to fully assess the public health impact of unregulated tobacco products, including the alarming increase in youth use of certain unregulated tobacco products, such as e-cigarettes and certain types of cigars. These facts highlight the need for regulation designed to prevent growing tobacco use that may lead to a lifetime of nicotine addiction and a range of potential serious health problems.

Moreover, novel tobacco products, such as e-cigarettes and hookah, are currently being marketed without companies needing to report their ingredients or harmful constituents. A final deeming rule will help FDA protect public health by requiring a review of all new products and health

related claims for regulated tobacco products in today's rapidly evolving marketplace.

Deeming will allow FDA to issue future regulations regarding these products, including regulations intended to reduce their harmfulness, if the FDA determines that such regulations would be appropriate in the protection of the public health. FDA's mandate is to protect Americans from tobacco-related disease and death, and ultimately, regulating additional tobacco products will have a positive impact on the health of our population. That is why we are undertaking this action today, and that is why we feel so excited about the path that we are embarking on.

I want to echo the Secretary's thanks to CTP for their tireless efforts on this important action to reduce the total of tobacco, and I want to turn over the discussion to Mitch Zeller, the tireless director of CTP who will provide many more details about the action that we're taking today.

Mitch Zeller: Thank you so much Commissioner Hamburg and thank you Secretary Sebelius for all of your leadership on this important public health issue. Reducing tobacco-related disease and death is one of the most critical public health challenges before FDA and this proposed rule would make a diverse group of previously unregulated tobacco products subject to FDA's science-based regulatory process.

When the proposed rule is finalized, FDA will be able to use powerful regulatory tools to help reduce tobacco-related disease and death. For example, the provisions in the Food, Drug and Cosmetic Act would automatically apply to newly deemed tobacco products and these include requirements to register and submit product and ingredient listings, a prohibition on new tobacco product marketing without prior FDA review, a

prohibition on direct and implied claims for either reduced exposure or reduced risk without FDA review, and authorization based on scientific evidence and a prohibition on free samples.

A deeming final rule would mark the first time that manufacturers of currently unregulated tobacco products would have to provide information about their ingredients and harmful constituents. Currently unregulated tobacco products would also have to undergo review by FDA in order to stay on the market or to be introduced as new products for sale. Now FDA recognizes it may be a challenge for manufacturers of newly deemed tobacco products -- including some e-cigarette manufacturers -- to identify what the law calls valid predicate to use the substantial equivalence that way and a valid predicate is defined by the statute as one that was on the market as of February 15, 2007.

For this reason, FDA is proposing that these manufacturers submit applications for premarket review of tobacco products, or what we call PMTAs. Submit PMTAs to FDA no later than 24 months following the effective date of a final deeming rule. During which time, FDA would not impend and to initiate an enforcement action for failing to have a marketing authorization and in addition, as long as the manufacturer has submitted one of those PMTAs within 24 months, FDA would not intend to initiate such an enforcement action against the product on the market while the application is still pending review at FDA.

So, as a practical effect of these proposed compliance periods, we would expect that most firms would continue marketing their tobacco products pending FDA's review of their marketing applications. In addition, when finalized, the rule would apply the following new requirements to newly deemed tobacco products. First, minimum age and identification restrictions to prevent sales to underage youth. Second, requirements to include health

warning labels and finally, a prohibition on vending machine sales unless that vending machine was located in a facility that never admits youth.

The deeming proposed rule does not include a ban on online sales or television advertising of e-cigarettes. However, once a tobacco product is deemed, FDA may put in place restrictions on the sale and distribution of those products including advertising and promotion restrictions. Those kinds of restrictions would be the subject of a separate rulemaking and a separate opportunity for public comment. FDA is also not proposing to categorically ban flavors of newly deemed products. In order to do this, FDA would have to issue through the rulemaking process a tobacco product standard under section 907 of the Food, Drug and Cosmetic Act, and FDA is currently assessing available research regarding the impact of flavors on tobacco product use and its funding research on this issue.

FDA is proposing different compliance dates for various provisions so that all regulated entities, including small businesses, will have adequate time to comply with the requirements of a final deeming rule. The proposed rule will be available for public comment for 75 days and while all comments and data, research and other information submitted to the docket will be considered, FDA is requesting comments in a number of specific areas that I'd like to highlight.

FDA recognizes that different tobacco products may have the potential for different public health impacts. Therefore, FDA is seeking comments, research and data on its proposed regulations to determine if there are any circumstances where public health considerations would lead to different regulatory approaches for different tobacco products. FDA recognizes that different tobacco products may have the potential for varying effects on public

health and is proposing two options for the categories of cigars that would be covered by this rule.

FDA is specifically seeking comment on whether all cigars should be subject to deeming and which are the provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars. FDA is proposing two options the categories of cigars that will be covered by this rule. Option one proposes to regulate all products that meet the definition of a tobacco product. Option two proposes defining a category of premium cigars that would not be subject to FDA's regulatory authority.

In the proposed rule, the definition - the proposed definition of premium cigars includes tobacco products that are wrapped in whole tobacco leaf, made by manually combining the wrapper, filler and binder, have no filter tip or non-tobacco mouth piece, have no characterizing flavor other than tobacco and have a certain minimum price point per cigar. Several outside parties contend these products may be used differently by consumers than other types of tobacco products.

FDA is seeking answers to the many health questions posed by products -- such as e-cigarettes -- that do not involve the burning of tobacco and inhalation of its smoke as the agency develops an appropriate level of regulatory over sight for these products. FDA is seeking comment in this proposed rule as to how such products should be regulated. Components and parts of newly deemed tobacco products would be included in the scope of this proposed rule. FDA is seeking comment on whether we should define components and parts of these newly deemed tobacco products and how those items might be distinguished from accessories of tobacco products, the proposed rule does not include accessories of the newly deemed tobacco products such as cigar cutters and hookah cases.

In conclusion, when finalized, a deeming rule would result in significant public health benefits including reducing sales to youth, helping correct consumer misperception, preventing misleading health claims and preventing new products from entering the market without prior scientific review by FDA. In addition, the deeming rule differs from most public health regulations in that it's an enabling regulation. It will allow us to propose further regulatory action on these and yet to be conceived tobacco products in the future under that standard of appropriate for the protection of the public health.

When finalized, the rule will represent a significant step in the agency's ability to effectively regulate tobacco products. FDA will play a vital role in protecting the public by reviewing all new products and health related claims for tobacco products in today's rapidly evolving marketplace and as we learn more about these products, the agency will have additional opportunities over the long-term to make a positive difference in the public health with tobacco use in this country. Thank you.

Jennifer Haliski: Thank you Mr. Zeller. At this time, ladies and gentlemen, we will begin the question and answer portion of the briefing. Although Mr. Zeller will take the majority of the questions, we also have a technical expert from the Center for Tobacco Products on the call. We are joined by Ms. Gerie Voss from CTP's Office of Regulations. As a reminder, this call is being recorded. When asking a question, please state your name and affiliation. Also please limit yourself to one question and one follow-up question so that we can get to as many questions as possible. Operator, we'll take the first question.

Coordinator: Yes. Our first question comes from Maggie Fox from NBC News. Your line is open.

Maggie Fox: I want to ask about the labeling requirement. My understanding is that when this regulation takes effect, it would automatically require warning labels on these products. Given how little we know about e-cigarettes, what do you propose there being in the label and what would be the process for determining the labeling language? Thanks.

Mitch Zeller: One clarification on your question, Maggie. The proposed warning labels would not take effect immediately. We're proposing that health warning labels would not go into effect until two years after the final rule is effective. But to the question about e-cigarettes, we are only proposing one warning label for e-cigarettes and that is an addition warning, reminding users that the product is addictive because it contains nicotine which is an addictive chemical.

Maggie Fox: I'm sorry. Who was speaking just then please?

Mitch Zeller: This is Mitch Zeller, director of the Center for Tobacco Products.

Maggie Fox: Thank you and can you tell me what you know, if anything, about the safety of nicotine?

Mitch Zeller: That's a complicated question. Nicotine, when regulated as a therapeutic product, has been on the market under the standard of safety and efficacy for over 30 years. So, nicotine gum, nicotine patch, nicotine lozenge, the prescription nicotine inhaler, is safe and effective when used according to the label to help smokers quit. But when it comes to e-cigarettes, it's the wild, wild west. We have e-cigarettes that are exploding in car chargers and wall sockets. We have people purchasing liquid nicotine cartridges and it's buyer beware. None of this is taking place in a regulated environment and that's why we're proposing this rule.

Maggie Fox: Thank you.

Coordinator: The question comes from Victoria Bekiempis from Newsweek. Your line is open.

Victoria Bekiempis: Hi there. Can you hear me?

Mitch Zeller: Yes.

Victoria Bekiempis: Hi. This call - so basically, here's what I'm wondering. A lot of the litigation from e-cigarette users to prevent regulation of e-cigarettes and their use and prohibitions on their use in public places hinges on the question well, what is an e-cigarette? How do you define an e-cigarette? For example, a lot of people who "vape", they'll have a device in which they're actually not vaping with any nicotine and it will be some type of flavored water vapor in the device that looks nothing like a e-cigarette whatsoever. So, their legal argument is well, is this an e-cigarette? What are you saying is an e-cigarette? So, that would be my question. How is FDA defining an e-cigarette especially when there is no nicotine involved which could be as much as 25% of the market?

Margaret Hamburg: This is Dr. Hamburg and we - our authority would be extended to products that were made or derived from tobacco, so that if the product didn't contain nicotine, it would really not be classified under our proposed deeming regulation but obviously, these products do raise other concerns. Mitch is the lawyer and he has some other observations.

Mitch Zeller: Just two other points just for the avoidance of doubt. In that scenario, there would have to be no other aspect of the product that was made or derived

from tobacco but your question started with, where can people use these products and what would be the relevant...

Victoria Bekiempis: No. I was just giving an example with - just citing an example from pro e-cigarette lawsuits that hinging from this prohibitions in public, that largely hinged on this question. Well, what is an e-cigarette and so, that was what I was concerned about. How are you all defining e-cigarette?

Margaret Hamburg: I think another element of your question was challenging to us as we were preparing this proposed rule is that the marketplace for tobacco products, including e-cigarettes, is evolving very, very rapidly. And the e-cigarettes that first emerged in the marketplace a few years ago looked very different than the ones that are currently available now, and there are a lot of different variations on the scene. And one of the things that we hope to be able to accomplish through this rulemaking process is to get a lot more information about what is actually out there. What are the components of these products and of course, the ongoing assessment of what are the potential risks to health.

Victoria Bekiempis: Okay, but non-nicotine things that look like e-cigarettes and non tobacco things would not be regulated by you no matter how much they seem to be e-cigarettes.

Mitch Zeller: As long as there's no part of the product that's made or derived from tobacco. That's the statutory definition.

Victoria Bekiempis: Okay. Thank you so much.

Jennifer Haliski: Operator, next question please.

Coordinator: Our next question comes from Michael Felberbaum, the Associated Press. Your line is open.

Michael Felberbaum: Good morning. So, I'm curious to see what's your response to members of Congress and public health organizations that say that these deeming regulations don't go far enough when it comes to electronic cigarettes addressing issues related to marketing and flavors that might be targeting or attractive to youth?

Margaret Hamburg: Well, I certainly understand -- this is Dr. Hamburg -- that there is a sense of urgency to get a better understanding and provide more regulatory oversight of e-cigarettes. As Mitch (Zeller) just mentioned, at the present time, with FDA having no authority to regulate these products, it is a bit of the wild, wild west. We have a legal regulatory framework within which we need to operate.

The deeming rule represents a very, very important foundational step in our ability to more broadly regulate these products and other tobacco products. There are a number of things, as you know, that will go into effect quickly with finalization of the deeming rule that will have clear benefits for health with regard to e-cigarettes and more broadly, including limits on the sale of these products to people under the age of 18, but with respect to other aspects such as the flavoring, we are required to do additional rulemaking bringing additional evidence to bear through the product standards requirement.

Jennifer Haliski: Michael, did you have a follow-up? Okay. Operator, we'll take the next question.

Coordinator: Our next question comes from Saundra Torry with USA Today. Your line is open.

Saundra Torry: Hello. Thanks for doing this. You mentioned that the public will have 75 days to comment on this. What is the maximum time in which you expect to finalize this rule?

Margaret Hamburg: Well, that is all we - hard to answer the question. What I can tell you is that we feel a sense of urgency to finalize the deeming rule. We want to have this period of comment. We're asking for additional information for consideration as we finalize the rule and we will take all of the input very seriously, but we are eager to see this process move forward towards the final deeming rule so that those new requirements, restrictions and oversight mechanisms will fall into place and also so that we can move to other regulatory activities that we think also are very, very essential to promote and protect the health of the public.

Saundra Torry: Can you mention any other points? You said that the ban on sales to those under 18 would be effective immediately when this is finalized. How about internet sales or any others that will be come effective? Can you list a few?

Margaret Hamburg: Well again, we need to have deeming in place for the issues around online sales or TV advertising. Once the tobacco product is deemed, we can put in place restrictions on the sale and distribution of those products including advertising and promotion restrictions, but those restrictions would require separate rulemaking and public comment.

Saundra Torry: I was talking about things like the sale on the internet or selling to those under 18. Would those go into effective immediately?

Margaret Hamburg: Under 18 yes.

Saundra Torry: But nothing else?

Mitch Zeller: No. The ban on vending machine sales goes into effective within...

Margaret Hamburg: Prohibition of free samples. Also, the requirement for companies to register with FDA and list their products, the requirement to submit a list of ingredients, requirements to ensure tobacco products aren't unadulterated and misbranded, the requirements that Mitch (Zeller) mentioned about prohibition of direct and implied claims that products reduce risks without FDA review and authorization based on scientific evidence and requiring newly deemed tobacco pipes to meet certain requirements or undergo review by the FDA in order to stay on the market or be introduced as a new product. Those are all aspects of the deeming rule itself that would apply as the rule becomes final.

Saundra Torry: So, internet sales are not part of that? That's one I was very interested in.

Mitch Zeller: No. The proposed rule does not contain a ban on internet sales but when the rule goes final, the prohibition on the sales to minors would apply to internet sales.

Saundra Torry: Thank you.

Jennifer Haliski: Operator, next question please.

Coordinator: Our next question comes from Tim Devaney with the Hill Newspaper. Your line is open.

Tim Devaney: Hey. Thanks for taking my question guys. I had two if you don't mind. My first one was if you could talk more about the public misconceptions that are out there about e-cigarettes and in part, the misleading claims coming from

these companies about whether they're healthier than cigarettes or not. If you could just talk about that? What's going on with that?

Mitch Zeller: That's a good question and at this point, I would say we have far more questions than answers about who is using e-cigarettes and how they are being used. Let me give an example. If someone is a pack a day smoker and they have no interest or ability to quit and they're going to continue to smoke a pack a day of cigarettes, a pack of cigarettes a day, for the rest of their lives and that hypothetical smoker substituted all of their combusting cigarettes for e-cigarettes, I think even with all the questions that we have, we can see that that person is likely to be substantially reducing their risk. That's a hypothetical.

The challenge for us as regulators is we're responsible for enforcing a law that has a population level health standard and our job is to figure out what are the net impacts at that population level of all the possible uses because there's a much greater proportion of smokers who are concerned about their health and are interested in quitting and what happens if instead of continuing down that pathway to quitting -- especially using FDA-approved safe and effective medicinal products -- they start engaging in what's called “dual use” and they're using e-cigarettes in situations where they can't light up and they wind up being less interested or motivated to quit. And this punitively less harmful product actually increases harm because all it does is serve as a bridge for health concerned smokers to get from their last cigarette to their next cigarette. We don't know what the patterns of use are.

We're funding massive studies to try to get a better handle on what the behaviors are but it's awfully complicated because it's going to be an assessment of what is the impact on initiation? What is the impact on cessation that's mandated by law and what are these use patterns so we can

best understand how to regulate emerging technologies like e-cigarettes in a manner that the law requires us to which is appropriate for the protection of the public health.

Tim Devaney: That sounds really interesting. It sounds like you don't know yet whether it's a gateway drug to traditional cigarettes.

Mitch Zeller: There are - experts have raised the concern that kids who initiate on e-cigarettes and CDC put out a study about six or seven months ago that showed that between 2011 and 2012, e-cigarette usage amongst middle school and high school age kids doubled in one year and experts are concerned that once a kid experiments with e-cigarettes in any initiation of any nicotine containing product is not good for public health but it's especially damaging if those kids become tolerant to nicotine, they get used to the nicotine and they then go on to seek their nicotine from combusting cigarettes and there is a concern that that is a pattern of use that might be out there.

Tim Devaney: I just wanted to - can I just clarify one thing? Right now, before the regulations, are kids allowed to smoke e-cigarettes? Or if you - currently, before the regulations, would they still not be allowed to buy these e-cigarettes from wherever they buy them?

Mitch Zeller: In the absence of this rule going final, there is no federal regulation or law that prohibits the sale of e-cigarettes to minors. That can only currently be addressed on a case by case basis at the state or local level.

Tim Devaney: Thank you.

Jennifer Haliski: Next question, operator. Operator, next question please.

Coordinator: Our next question comes from Shannon Bond from Financial Times. Your line is open.

Shannon Bond: Hi. Thanks a lot. I was wondering if you could talk a little bit more about why you didn't decide to include any restrictions on advertising -- specifically on TV, radio, billboards -- at this time? I know you've said that's something that could be put into place later, but why was it not included in this round in the deeming regulations?

Mitch Zeller: This is Mitch. As the Commissioner said, in order to impose restrictions on advertising, marketing and promotion, that would have to be the subject of a separate rulemaking and it's like walk before you run. In order to be able to do a rulemaking on advertising, marketing and promotion, you have to have jurisdiction over the products. In order to have jurisdiction over the products, this rule has to go final and be in effect. So, that's why we call this foundational. That's why this is a historic day.

There are these entire category of products out there that many people think are safer than cigarettes including unregulated combusting products that people think are safer than cigarettes, and the whole point of being regulated under our statute is to bring a public health based, evidence-based, regulatory approach to product end consumers, protecting the public health and things like, what are the most appropriate restrictions on advertising, marketing and promotion would have to be the subject of an evidence base that could support a separate rulemaking but we only get to do that or even consider doing that if deeming goes final and is in effect.

Shannon Bond: Is the agency concerned about some of the advertising practices that are currently in place?

Mitch Zeller: I think that there are a number of experts out in the field -- people who have been working in the area of tobacco control for decades -- who could tell you that they are very concerned about how e-cigarettes are being advertised in a way that they think might be very appealing to kids.

Jennifer Haliski: Operator, next question please. Operator?

Coordinator: Our next question comes from Eliza Gray, Time Magazine. Your line is open.

Eliza Gray: Hi. Thank you. I had a question about the substantial equivalence. You made it clear that e-cigarette companies could market their products while they wait for approval of their application for a new product but I wasn't clear on whether that's only for the first two years after the regulation. In other words, after that two year period, will they then have to wait before they can market a new product? I know there's some concern with e-cigarettes because unlike combustible cigarettes, there are a lot of technologies that change quite frequently and concern that perhaps, over time, it might take the FDA too long to say yes to the next battery. While they're waiting, five new batteries will come on the market. So, I was wondering if you could clarify that and then maybe talk a little bit about that process.

Mitch Zeller: Sure. So, here's what we're proposing. We're proposing a compliance policy that says for a two year period -- after the final rule goes into effect -- currently, market -- let's just talk e-cigarettes. Currently marketed e-cigarettes could remain on the market and manufacturers could introduce new e-cigarettes during this two year period as long as before the end of that two year period -- for either currently marketed or newly marketed products -- they submit an application to us either to demonstrate that the new product is substantially equivalent, to prove that they should be exempted from the substantial equivalence requirement which is a separate pathway, or the

premarket - the new product application and as part of this compliance policy, as long as one of those applications is submitted before the end of that two year period, we're proposing that once the two year period ends, those products could remain on the market until we've ruled on a specific application. What that means is on the first day after the 24 month period ends, no new products could be brought to market without an application being filed before hand that we made a decision on.

Jennifer Haliski: Was there a follow-up?

Eliza Gray: I guess the follow-up would just be do you think that the agency - I mean, are there any concerns that the agency has enough resources to deal with the high level of potential new applications given how many more potential changes in product could happen with e-cigs in terms of new technologies? I mean, with a regular tobacco cigarette, changing the flavor profile or the paper wrapping around it is not as major or constant as the little micro changes in the technology with e-cigs. So, I just wondered if there's anything else you could say about that in terms of the swiftness with which the agency can respond to new applications after that two year period has ended?

Mitch Zeller: I think it's a fair question and we're confident that we're up to the task. Just last week we announced that for currently marketed products, we are completely caught up with the queue for the so called regular substantial equivalence submissions and the regular submissions are for those products not currently on the market and as of March 24, we are completely caught up with the queue which means that as soon as the application comes in, we commence scientific review. So we are confident that we will continue to make progress like that going forward and that we will be up to the task regardless of what the volume is after deeming goes final and many more

products are the subject of either substantial equivalence or new product applications.

Eliza Gray: Thank you.

Jennifer Haliski: Operator, next question please.

Coordinator: Our next question comes from Gitika Kaul, ABC News. Your line is open.

Gitika Kaul: Hi there. What do you guys think the trade association and the industry folks who are saying that e-cigarettes are more technology products and not tobacco products and therefore shouldn't necessarily be under FDA's rule under the Tobacco Control Act?

Margaret Hamburg: Well I think as we talked about before, there is a legal definition of a tobacco product and e-cigarettes contain nicotine that is manufactured or derived from tobacco. It's the legal definition of a tobacco product and if the proposed rule that we are announcing today is finalized, then e-cigarettes clearly fit within our regulatory jurisdiction.

Jennifer Haliski: Operator, next question please.

Coordinator: Next question comes from Paul Weingarten, Chicago Tribune. Your line is open.

Paul Weingarten: Hi. Thank you for taking the question. Is it fair then to say - I mean, from what I've been gathering is that the science is heavily suggesting that e-cigarettes are less harmful than real cigarettes but not harmless. Is that a fair way of putting it?

Mitch Zeller: I don't think we know enough to say anything remotely definitive like that. We're funding dozens of studies to get answers to questions about the safety of these cigarettes. We can't even tell you what the compounds are in the vapor and in the absence of regulation, the companies aren't required to give us any information. So, I think it's premature to make a statement like that. I think that in general, a product that doesn't contain and burn tobacco leaves has the potential to reduce toxicity and reduce harm but it comes down to two fundamental questions that we do not have answers to. Who is using those products and how are they being used?

In my prior example, I tried to point out it depends upon who the user is. If it's that pack a day smoker who would've continued smoking and they are completely off cigarettes that's one thing but what about the great majority of health concerned smokers who might be interested in quitting who as a result of starting to use these e-cigarettes find themselves less interesting in quitting.

Paul Weingarten: Right, but I'm just talking about - it's like my kid who never smoked, who aren't smokers but are using - what kind of - the risk to their health certainly is less than if they smoke cigarettes. Let's assume they're not smokers right?

Mitch Zeller: I'll defer to the Commissioner on the more medical part of this, but I can tell you that kids should not be initiating even an e-cigarette that contains no burning tobacco leaves because of the effect that nicotine can have on the developing brain.

Paul Weingarten: Right. Okay.

Margaret Hamburg: I think that's right and also going back to Mitch's earlier point about we need to understand the patterns of behavior. If a kid starts with e-cigarettes, nicotine being addictive, it creates a heightened vulnerability that they will go

on to use other tobacco products as well and we know that there are an increasing array of tobacco products in the marketplace and many of those are attractive to youth in terms of flavorings, et cetera. So, one can easily imagine a cycle that will bring with it serious dangers for health.

Jennifer Haliski: Operator, next question please.

Coordinator: Next question comes from John Tozzi, Bloomberg Business Week. Your line is open.

John Tozzi: Hi. You guys mentioned that you're funding dozens of studies looking at the public health consequences. I'm wondering if you can tell us and help us understand what, if anything, in this rule will contribute to the information available and the evidence base available about the public health effects of e-cigarettes?

Margaret Hamburg: Well, I'll start and Mitch will continue. I mean, I think the research is already being undertaken and it's very, very important. It will give us a lot of insights that will be of enormous use to better understand the risks of these products. It will give us an evidence base for future regulatory actions should we choose to take them in order to product public health but I think one of the things that will be extremely helpful as these efforts go forward is to be able to have the regulatory oversight of products so that companies will be required to tell us what is in these products, how they're making them and we'll be able to get the full range of information about the products they are producing and how. So, I think that the research we're already funding we'll continue to support will be greatly supplemented by the additional information that we can gain through finalization of the deeming rule and the application of additional requirements.

Mitch Zeller: The only thing I would add is just one concrete example there. The companies will be required to report information to us on a brand and sub brand basis on the levels of compounds in the vapor, the levels of compounds added to the products. We don't have that information now. The public doesn't have that information now and it will help us do our job in a regulated environment when it's mandatory that companies submit that kind of information to FDA.

Jennifer Haliski: Operator, I know that we have one more question in the queue. Could you also please prompt our participants as to how they might ask a question if we have others that might want to ask a question before we conclude? And then we'll take the next question.

Coordinator: Yes. As a reminder, if you would like to ask a question, please press Star 1. Remember to unmute your phone and record your name clearly when prompted. Our next question comes from Delthia Ricks, Newsday. Your line is open.

Delthia Ricks: This is for Mr. Zeller and thank you for taking this question. You mentioned very, very briefly that there are problems with explosions with the e-cig devices. I'm assuming that's when they're being charged. Can you elaborate on that a little bit just so that I understand what some of the problems are with them?

Mitch Zeller: I can only tell you, because we don't have the power to compel provision of information to us, until these products are regulated what we, like consumers, would be reading in the newspaper and from time to time. There are newspaper and media accounts of these cigarettes that have been charged in car lighters, in the cigarette lighters in cars, that exploded. There have been reports of e-cigarettes being charged in wall sockets at home that started fires. It's why we say it's buyer beware in the currently unregulated marketplace.

Delthia Ricks: Thank you very much.

Jennifer Haliski: Operator, next question please.

Coordinator: Our next question comes from Kathleen Doheny. Your line is open.

Kathleen Doheny: Hi. Kathleen Doheny, covering for WebMD. Two quick questions or one quick question and a follow-up. Can you be a little closer to that gap on the timeline question? There's the 75 day comment, then there's the two year period that they have to compliance. Can you fill that gap? What happens - when might the rule be finalized before that 24 month?

Margaret Hamburg: This is Dr. Hamburg. It is very hard for us to really give you an estimate because after the comments come in, then we need to go through those comments in a systematic way and integrate information that we obtained through that process into our final rulemaking so that - what I can say is that we are very, very eager to move forward because we think this is a very important new proposed rule. We would like to see it go final so that we can get some of the kinds of information and new requirements on products that we've been talking about and also so that we can continue efforts in other areas, regulatory actions, that might build on the deeming rule as part of our new authority to regulate a fuller range of tobacco products.

Kathleen Doheny: Could you give us a year when this might be finalized?

Margaret Hamburg: No. We really cannot. It would be just speculation.

Kathleen Doheny: Okay.

Jennifer Haliski: Operator, next question please.

Coordinator: Question comes from Phil Boffey, New York Times. Your line is open.

Phil Boffey: Thanks. I'm curious - as I understand it, after the two year - one day after the two year period elapses, manufacturers have to come in and have FDA review applications for new products and I guess products that will remain on the market. What is it that the FDA can then do? After you do your review, do you have to approve or disapprove the marketing or what exactly happens after your review?

Mitch Zeller: What we would do is depending upon the order that was requested, it would fall into either the substantial equivalence bucket or the new product bucket, we would then make a science based determination about whether there was an adequate science base to support a product being allowed to come to market either because it was substantially equivalent to a predicate product or if it's under the new product pathway because it's appropriate for the protection of the public health. The critical demarcation there is after that two year period ends, no new products can be brought to market under this proposal until we've made a decision on one of those kinds of applications.

Phil Boffey: So in other words, you have to approve it. You can say, “No, you can't bring it to market”?

Mitch Zeller: That is correct.

Phil Boffey: Okay.

Jennifer Haliski: Thanks. Thank you. That was our last question. Ladies and gentlemen, this concludes today's media teleconference. Thank you for your participation. A

replay will be available in about an hour and will be up until May 30. If you have follow-up questions, please don't hesitate to contact the FDA's Office of Media Affairs. Our phone number is 301-796-4540. Thank you.

Coordinator: Thank you and that concludes today's conference. All parties may disconnect at this time.

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